Declaration in accordance with 37 CFR 1.132

I, the undersigned Lior Rosenberg MD, a citizen of Israel residing in Omer Israel hereby declare a follows:

1. I am involved in Plastic Surgery and Wound Care since 1974 and serve for the last 25 years as the chairman of the Department of Plastic & Reconstructive surgery at Soroka University Medical Center (including the units for Burns, Hands, Craniofacial Deformities, Reconstruction, Skin Oncology and Hard To Heal Wounds) in Beer Sheva and the Unit for Craniofacial Deformities in Meir Hospital, Kfar Saba. I am a full professor of Plastic & Reconstructive surgery at The Ben Gurion University of the Negev. I founded and chaired for two decades the Center for R & D in Plastic Surgery at the Ben Gurion University of the Negev. I was and still am involved in numerous clinical and preclinical trials many of them in the area of wound healing. Some fruits of my R & D activities resulted in the foundation of biotechnology, pharmaceutical and devices companies (Mediwound LTD, 4MED LTD, and LRR&D LTD).

2. My CV is attached to this declaration

3. I was requested by the applicants to review the documents regarding the US Patent Application Serial number 10/560,063. With the hindsight of reviewing all what has been said and written, it is my impression that some crucial topics were addressed but some biological/medical issues, mainly regarding inflammatory reaction and wound care process especially relating to the issue of small foreign bodies were not reviewed.

4. As far as I understand, in the applicant's invention they describe the following stages (I will use a slightly different terminology in order to illustrate my understandings):
   A. Causing localized trauma at the site and depth of the encapsulated pigment's particles (mainly superficial down to the mid-deep dermis). This localized trauma has multitudes of outlets to the skin surface.

B. It is the inventor's proclaimed intention to **cause** acute infectious-inflammatory reaction "*...the method involves "encouraging infection", which may aid the pigments to migrate ...*" (page 10 lines 12-13) and **not** to heal wounds (not unlike the *Laudable Pus* and the *Seaton* of old...). The goal of this inflammatory reaction as well as the mechanical action of the needles repeatedly penetrating and being withdrawn from the skin is to free the minute encapsulated foreign bodies within the dermal cells and matrix, to increase the target area hydration (inflammatory edema, serum/lymph sucked into the tissue by vacuum and possibly even external infiltration of the treated area with saline/water as claimed pending Claim 14.

C. Actively sucking the tissues debris, pigments and interstitial fluids through the punctured holes "*The aqueous mixture and cellular debris in the punctured area of skin are drawn into the pad*" (page 8 lines 7-8).

5. Once these three principles are understood the means that the inventors use are direct and innovative in their combination.

   A. The localized trauma is inflicted by the same means and in the same way that originally has been used to implant the pigment particles: multiple, depth-regulated needle punctures that dislodge the encapsulated pigment granules from the cells and dermal matrix. This mechanical trauma not only initiates acute inflammatory response well known to science but also opens conduits from each micro trauma site (needle prick) to the skin surface.

   B. As mentioned, the trauma-induced inflammatory process increases tissue fluids content in the form of interstitial edema, serum/lymph extravasation and even some capillary bleeding. These fluids may spill over through the needle conduits but this spillage depends on the pressure differences (that is not great) and the conduit's patency. A needle prick **will not** remain patent for long; it will be closed in few seconds by fibrin or blood clot. Using any absorbent material or dressing will clear away the spilled-over fluids and particles but will not clear those in the tissue's interstitium. This will cause the pigment particles probably to be dislocated from their original site in the dermal matrix but to remain in the tissue and re-implant again, mostly in the dermis, causing at best blurring of the tattoo lines but not removing them.

C. In view of these facts, the inventors added another crucial stage in their protocol: forceful, active drawing of the interstitial fluids and the particles it contains. It is done by two means: physical and optionally pneumatic.
Using hygroscopic dressing has more or less the same effect as the application of a vacuum but in a slightly different mechanism. The formidable hygroscopic force sucks out the fluids together with the tissue's debris and tattoo's pigments. Obviously the purpose of the applicant's dressing (paste) is **not** to heal wounds, on the contrary: The purpose in addition to providing the hygroscopic force in order to maximize the amount of pigment that can be removed from the dermis in the time interval before either the puncture holes close is to continue and irritate (to a certain point) the area in order to increase inflammation, swelling and "weeping". By doing so it also keeps the conduits open and functional (draining).

6. Nowhere in the literature to the best of my knowledge is a pinpoint (literally!), well aimed trauma inflicted in order to dislodge micro, intradermal foreign bodies followed by hygroscopic suction to remove the dislodged particle.

7. The hygroscopic paste differs substantially from the patented improved hydrocolloid dressing (Auguste) probably in light of their respective functions. The hydrocolloid dressing is destined to create a long lasting equilibrium at the wound's surface absorbing excess liquids but preventing desiccation thus, providing favorable condition for wound healing. The salt paste should exert a violent sucking force on the injured target area, absorb as little fluids as there are and keeping the area inflamed and the needle conduits weeping. So, these two products are using two different principles: The difference is between Hygroscopic (tonicity) and Absorbent (liquid content), the first is ***force*** and the second: ***volume***. The improvement of the hydrocolloid consists of adding the Polysorbates (ESFAE) that increase **only** the content's capacity of the hydrocolloid (volume). It **does not** increase and is not intended to increase the tonicity (hygroscopic force) of the hydrocolloid. The hydrocolloid inventors are very proud that their dressing is non irritant.

The salt-based granular paste has a different main function: to be strongly hygroscopic. The absorption capacity (volume) is of very secondary importance as the volume of the absorbed fluids is minimal and the time of exposure is very short but the hygroscopic force causes "*The aqueous mixture and cellular debris in the punctured area of skin are drawn into the pad*" (page 8 line 7-8). The importance of increasing/maintaining the inflammatory process is clearly voiced "*...the method involves "encouraging infection", which may aid the pigments to migrate ...*" (page 10 lines 12-13) and the raw "table salt" does just that.

The experimental results given in the tables in column 15 of Auguste, et al. provide another indication of the difference between another indication of the difference between the bandage of Auguste, et al. and the pad of the invention containing the salt-based granular paste. These tables list the amount of solution absorbed per hour by different formulations of Auguste's bandage. The largest value is $1900g/m^2 = 1.9g/cm^2$. This is only about 40% of the amount of aqueous mixture that can be drawn up by a pad of the invention in one third of the time according to the example on page 8, lines 11-13 of the application.

8. **Conclusion**

The inventors present an ingenious but simple system for removing imbedded foreign bodies (such as tattoo) by:

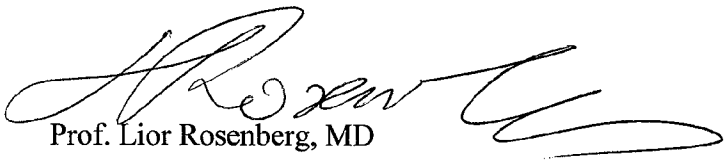
A. Recreating the original causative trauma (needle puncturing)
B. Modulating local inflammation (educated and controlled use of hygroscopic forces, i.e. the salt-based granular paste, in combination with antimicrobial agents)
C. Active suction of the fluids, debris and pigments by hygroscopic forces

In spite the fact that all components of the system are known and may be used in medicine in one way or another, in view of my knowledge of The Art this combination and sequence of actions and means is clearly innovative, feasible and answers an unmet need of many.

9. I hereby declare that all statements made herein of my own knowledge are true and that all statements made herein on information and belief are believed to be

true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the subject application or any patent issuing thereon.

10. The name and signature below are my name and signature.



Prof. Lior Rosenberg, MD

This day of September 11, 2009